MERIDIAN CO., LTD.

3F., 997-4, Medison Venture Tower, Daechi-Dong, Kangnam-Gu
SEOUL, KOREA
Tel : 82.2.2194.3300 Fax : 82.2.2194.3333

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

APPLICANT'S NAME/ADDRESS :	MERIDIAN CO., LTD. 3F Medison Venture Tower 997-4 Daechi-Dong Kangnam-Ku Seoul, Korea
CONTACT PERSON :	Soo Rang Lee
COMMON/USUAL NAME :	Galvanic Skin Response Measurement
CLASSIFICATION NAME :	Galvanic Skin Response Measurement
OWNER/OPERATOR NUMBER :	9038705
CLASSIFICATION :	The Galvanic Skin Response Measurement Device is classified into Class II under 21 code of Federal Regulation 82. 1540
PERFORMANCE STANDARD :	MERIDIAN CO., LTD. is not aware of any Special Controls or Performance Standards established for Galvanic Skin Response Measurement Device under Section 513

and 514, respectively, of the Food and Drug and Cosmetics Act.

SUBSTANTIAL EQUIVALENCE :

MERIDIAN CO., LTD. believes the MERIDIAN-Portable is substantially equivalent to the MERIDIAN-II and MERIDIAN-Plus

Electrical safety of the MERIDIAN-Portable are achieved by means of reinforced or double insulated parts. Electrical isolation of at least 4000Vac between Applied Part(patient circuit) and Live Part. An isolation transformer isolates the primary line current from the secondary electronics of the system when the AC adapter is connected to the system. The connectors of the probe and other accessories are uniquely designed to prevent accidental connection to an AC power outlet.

The MERIDIAN-Portable system underdone various electrical safety tests and certify the conformance to the following standards (See Attachment 3) :

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.

2. CSA Std. No. 601.1-M90, Safety of Medical Electrical Equipment, Part I, General Requirements for Safety, including Supplement 1 and Amendment 2

3. UL Std. No. 2601-1 (2^{nd} Edition), Safety of Medical Electrical Equipment, Part I, General Requirements for Safety

4. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

In summary the MERIDIAN-Portable meets or exceeds all the safety requirements for a medical device in its class. Our dedication to safety is

evidenced in the many extra steps we have taken to insure a safe product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Mr. Soo-Rang Lee
Research and Development Manager
Meridan Company, Ltd.
3F Medison Venture Tower
997-4 Daechi-Dong
Kangnam-Ku
Seoul, Lorea

Re: K010897
Trade/Device Name: Meridan Portable
Regulation Number: 882.1540
Regulatory Class: II
Product Code: GZO
Dated: March 22, 2001
Received: March 26, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

PMN 510(k) Number : K010897

Device Name : MERIDIAN-Portable

Indications for Use :

The MERIDIAN-Portable, Galvanic Skin Response Measurement Device, is intended use in for the measurement of galvanic skin response.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010897